



BE AWARE & TAKE CARE:
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The Script

C A L I F O R N I A B O A R D O F P H A R M A C Y JANUARY 2001

Changes in Pharmacy Law for 2001

Effective January 1, 2001, enacted legislation has made both substantial and minor changes to pharmacy law, and these changes are summarized below. The exact language of the new and amended statutes noted below can be found in "Law Update," beginning on page 13.

**AB 2018 (Thompson, Runner & Migden)
Chapter 1092,
Statutes of 2000**

Triplicate Prescriptions

H&SC 11161, 11163 repealed, and 11164—eliminate the restriction on the number of triplicate forms a prescriber may order (previous law limited prescribers to 100 triplicate forms per month). The bill also eliminates the requirement that a triplicate be written entirely in the hand of the prescriber. After January 1, 2001, the prescriber is required to sign the triplicate. The remaining information required on the triplicate form can be written or typed by the prescriber or the prescriber's employee. Lastly, the bill permits pharmacists to correct errors on a triplicate after consulting with the prescriber. When the pharmacist makes a correction, the prescriber is obligated to mail or fax a correction to the pharmacist within seven days of dispensing the prescription.

**AB 2240 (Bates)
Chapter 293,
Statutes of 2000**

Electronic Prescriptions

B&PC 4070, 4071.1 and H&SC 11164.5—eliminate the requirement that pharmacists reduce electronic data transmission prescriptions to writing if the computer systems used in the transaction meet the following standards:

- Records must be maintained for three years;
- The pharmacy can immediately produce a hard copy report that includes all the prescription and dispensing information;
- The computers do not permit electronic records to be altered or destroyed for three years;
- The computers require a pharmacist to personally authorize any change in the records;
- The computer records the substance of any change, the date of the change, and the identity of the pharmacist authorizing the change.

Once federal law is changed to allow the electronic transmission of controlled substance prescriptions, and

See Law for 2001, Page 6

In This Issue

Changes in Pharmacy Law for 2001	Front Page
President's Message	Page 2
Pharmacist Manpower Task Force	3
Application to Store Pharmacy Records Offsite	5
Answers to Questions on Triplicate Law Changes	8
Rx for Good Practice	10

Live Scan Fingerprinting is Here	11
Pharmacy Board Meetings	12
Law Update	13
How to Find Prices for Medi-Cal's Top 50 Prescription Drugs ...	26
Change of Address form	27



President's Message

By Robert H. Elsner
President, Board of Pharmacy

On January 23, 2001, the Board's newly appointed Pharmacy Manpower Task Force—a working group to insure patient access to pharmacist's care and prescription services—will hold its first of several (perhaps many) public meetings. Comprised of representatives of various pharmacy stakeholder organizations and entities, including the four schools of pharmacy, the task force will continue to meet over the coming year under the chairmanship of former Board President, Holly Strom, R. Ph., who also currently chairs the Board's Licensing Committee.

This meeting will be an open forum to encourage comments and recommendations from the profession and others. Future meetings will also allow for both written and verbal presentations, prior to the task force deliberations and crafting of a formal report. How long this task force will require to accomplish its charge and make recommendations back to the Board is uncertain. Early projections are that there will be a minimum of four meetings and possibly more—all open to the public and the profession.

The scope and format of the task force will be determined by the group itself, with the ultimate goal of coordinating efforts of the pharmacy profession to seek solutions to the pharmacy shortage in California. Though the manpower situation exists nationally, it is particularly critical in many of our state's communities and regions.

At its October meeting, the Board heard testimony—certainly a “preview” or glimpse of what the task force will be hearing at its initial meeting. Nearly 18 pharmacists, mostly representing the California Retailers Association, as well as several other individuals, presented testimony citing some of the problems they face, along with some suggested solutions:

- Allow reciprocity and accept the NABPLEX in California.
- Make the California exam all multiple choice, available online three times per year at testing centers.
- Allow central processing of prescriptions.
- Eliminate the clerk/typist from the ratio, and expand their duties.

- Revise the pharmacy technician training requirements.
- Allow pharmacists-in-charge to supervise more than one pharmacy at a time.
- Adopt regulations to expand pharmacy technician duties.

There was no debate nor Board response to these recommendations—not only because of time constraints but also because it would have been premature to pre-empt the function of the task force. Clearly, some of the recommendations may not be embraced by all stakeholders, or even by the Legislature—for a variety of reasons. On the other hand, some of the concepts may well be accepted in one form or another. But it was understood that these proposals, undoubtedly along with many others, and from many other interested parties, would be formally presented to the task force for its review and consideration.

While, as previously acknowledged, there are no simple answers to solving California's pharmacist shortage, the Board of Pharmacy and the Pharmacy Manpower Task Force are committed to trying and will have some specific recommendations in coming months. Again, all interested parties are encouraged to attend the task force meetings. The dates and locations of the meetings will be published in *The Script* and available on the Board's website: www.pharmacy.ca.gov.

June 2000 Exam Results

After each California pharmacist licensure exam, the Board receives many inquiries regarding the pass/fail statistics. These statistics cannot be released to the public until they are presented to the Board. The June 2000 exam results were presented at the October Board meeting and can now be shared with everyone.

The exam consists of two components—multiple-choice and essay—and to pass, candidates must achieve a score of at least 75 on each segment. Of the 1,065 candidates taking the exam, 622 (58.4%) passed, 130 (12.2%) failed the multiple-choice segment, and 313 (29.4%) failed the essay segment.

The passing rate was higher than that of the June 1999 exam when 539 (56.7%) of the 950 candidates passed.

Interestingly, the passing rate for the 555 California pharmacy school graduates in June 2000 was 75.3%, and 39.7% for the 411 other U.S. pharmacy school graduates. For the 99 foreign pharmacy school graduates, the passing rate was 25.3%.

PHARMACIST MANPOWER TASK FORCE MEETS JANUARY 23

Over the last year, there has been much attention directed to the nationwide pharmacist shortage. The Board of Pharmacy acknowledges that such a shortage exists in the various parts of California and has concerns on how this shortage impacts the availability and safe delivery of pharmacist care to patients in these affected areas. The Board, therefore, has formed the Pharmacist Manpower Task Force—a working group to insure patient access to pharmacists' care and prescription services—to seek solutions to the pharmacist shortage and to coordinate the various efforts that may be currently underway by interested and affected parties. The task force will include Board members, Holly Strom, R.Ph., and Don Gubbins, Jr., Pharm.D. and other profession and academic representatives:

- Fred G. Weissman, Pharm.D., J.D., Associate Dean for Academic Affairs, USC School of Pharmacy
- Katherine Knapp, Ph.D., Director for the Center for Pharmacy Practice Research and Development and Professor of Social and Administrative Sciences, Western University of Health Sciences
- Donald Floriddia, R.Ph., Ph.D., Associate Dean for Student Life, University of the Pacific
- Lloyd Y. Young, Pharm.D., Chairman of the Department of Clinical Pharmacy, USCF
- Harold J. Washington, Jr., Pharm.D., President of the California Pharmacists Association
- Alan Endo, Pharm. D., FCSHP, Director of Pharmacy, Riverside Community Hospital, California Society of Health System Pharmacists
- Dave Fong, Pharm.D., Senior Vice President of Pharmacy, Longs Drug Stores, California Retailers Association
- Nancy Stalker, Pharm.D., Vice President of Pharmacy Services of Blue Shield of California, California Association of Health Plans
- Ralph Duff, Sr., Pharm.D., California Employee Pharmacists Association
- Ralph Vogel, Pharm.D., President and Executive Director of the Guild for Professional Pharmacists
- John Perez, Director of Political Affairs, Local 324, United Food and Commercial Workers
- Arnold Godmintz, Consumer Representative
- Frederick Mayer, R.Ph., M.P.H., President of the Pharmacists Planning Service, Inc.
- Wayne Heine, California State Department of Personnel Administration

The task force anticipates holding at least four one-day meetings, which will be open to the public. **The first meeting is scheduled for January 23, 2001, at the Sheraton Gateway Hotel at the Los Angeles airport.** The dates and locations of subsequent meetings will be published in The Script and available on the Board's website: www.pharmacy.ca.gov.

The Board is very committed to this project and is seeking everyone's support and active participation.

Waivers for offsite records storage

As of October 2000, section 1707 of the California Code of Regulations allows Board-licensed entities to store records offsite, pursuant to a completed and Board-approved waiver form. Please see pages 4 and 5 for instructions and an application to store pharmacy records offsite. The exact language of section 1707 can be found in "Law Update" under California Code of Regulations on page 25.



**California State Board of Pharmacy**

400 R Street, Suite 4070, Sacramento, CA 95814-6237
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Instructions for Completing an Application for Waiver To Store Records Offsite

NOTE TO APPLICANT: *If waiver is approved, store approved waiver in the pharmacy with the self-assessment form.*

California law requires pharmacies and other licensed facilities to maintain records and other documentation of the acquisition and distribution of dangerous drugs and dangerous devices for three years. Additional requirements exist in federal law. California law requires that these records be retained in readily retrievable form. Specific provisions regarding the storage and maintenance of records are found in various California laws, including:

Business and Professions Code sections 4081, 4105, 4333
Health and Safety Code sections 11159, 11164, 11179, 11205
Code of Regulations, Division 17, Title 16, sections 1707, 1707.1, 1717.4, 1718

The Board of Pharmacy is authorized to grant waivers to allow offsite storage of records under specific provisions provided in California Code of Regulations section 1707. The attached form is the application for the waiver for offsite storage of pharmacy records. Other board-licensed facilities may obtain waiver applications by contacting the board. A copy of the regulation is attached for your information.

All records stored offsite must be kept in a secure area to prevent unauthorized access. Examples of reasonable storage areas are records maintenance facilities or commercial storage centers. The licensee must be able to produce the records within two business days upon the request of the board or another authorized officer of the law. The board requests that the waiver, if approved, be kept in the pharmacy.

All prescription records for non-controlled substances must be kept in the pharmacy for one year from the date of dispensing. All prescription records for controlled substances must be kept in the pharmacy for two years from the date of dispensing.

A waiver for offsite storage of records is not needed if the records are kept in a storage area at the same address or adjoining the licensed premises.

The Board of Pharmacy will review the information you provide on the attached form. If the waiver for offsite storage of records is approved, a signed copy of the form will be returned to you within 30 days. However, until you receive a board-signed copy of the form, offsite storage of records is not authorized.

A new waiver for offsite storage of records is needed if the records are moved to a different offsite location.

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APPLICATION TO STORE PHARMACY RECORDS OFFSITE

Upon return of the signed, approved waiver from the board, please keep the signed copy in the licensed premises with the self-assessment form.

Please type or print

Name of pharmacy:					Pharmacy license number:
Address of pharmacy:	Number and Street	City	State	Zip Code	Telephone number of pharmacy
Address of where records will be kept:	Number and Street	City	State	Zip Code	Telephone number of off site location:
Name of person requesting waiver:					Position with pharmacy:
Name of pharmacist-in-charge:					California pharmacist license number:

The board may cancel the authority to store required records offsite.

The pharmacy and the pharmacist-in-charge listed above have not failed to produce records pursuant to section 4081 of the California Business and Professions Code or falsified records covered by section 4081 of the California Business and Professions Code within the proceeding five years.

I certify under penalty of perjury of the laws of the state of California that all information provided on this application is true and accurate and the pharmacy will comply with requirements for section 1707 of the California Code of Regulations.

Signature of person authorized to request waiver

Print Name

Date

Signature of pharmacist-in-charge

Print Name

Date

OFFSITE WAIVER APPROVAL

Waiver Number:	Date Approved:
Board-Authorized Signature:	

Law for 2001*Continued from Page 1***AB 2899 (Committee on Health) Chapter 858, Statutes of 2000**

the federal rules are approved by the Board and the Department of Justice, this bill will permit such transmissions in California.

Chart Orders

B&PC 4019—permits a health care provider in a hospital to sign medication orders for another provider's patient. Current law requires the patient's health care provider to sign all chart orders on his/her next visit to the hospital.

SB 550 (Johnston) Chapter 8, Statutes of 2000**Dronabinol**

H&SC 11056—(effective March 29, 2000) rescheduled dronabinol (or Marinol) from a Schedule II controlled substance to a Schedule III controlled substance. Criminal penalties for violations related to dronabinol remain those for a Schedule II controlled substance.

AB 1496 (Olberg) Chapter 837, Statutes of 2000**Medical Device Retailers**

B&PC 4139—(effective July 1, 2001) moves the medical device retailer (MDR) program from the Board to the Department of Health Services (DHS). After that date, each MDR must apply to the DHS for licensure as a "home medical device retail facility." Because the amount of over-the-counter medical equipment that is sold pursuant to a prescription has increased, the number of facilities to be licensed will likely also increase. The Board will continue to issue and renew MDR licenses until July 1, 2001, and those licenses will be valid for one year after the date of issue. After July 1, 2001, any entity seeking to obtain or renew a license must apply to the DHS. During July 1, 2001, to July 1, 2002, MDRs who are licensed with the Board must apply for licensure with the DHS. Affected MDRs will receive information about the transition in the future after the details have been worked out. The bill also moves the exemptee examination and registration provisions for MDRs to the DHS.

SB 929 (Polanco) Chapter 676, Statutes of 2000**Optometric Prescribing**

B&PC 3041—expands prescribing authority to allow optometrists who are certified to use therapeutic pharmaceutical agents to prescribe the following drugs for the treatment of eyes:

- All oral analgesics that are not controlled substances.
- Codeine with compounds (three-day restriction).
- Hydrocodone with compounds (three-day restriction).
- All topical anti-allergy agents (including steroids).
- All topical anti-inflammatories (including steroids).
- All topical antibiotic agents.
- All topical hyperosmotics.
- Topical anti-glaucoma agents.
- All oral antihistamines.
- Prescription oral nonsteroidal anti-inflammatory agents (three-day restriction).
- All topical antiviral medications and oral acyclovir.
- The following oral antibiotics:
 1. tetracyclines
 2. dicloxacillin
 3. amoxicillin
 4. amoxicillin with clavulanate



5. erythromycin
6. clarythromycin
7. cephalixin
8. cephadroxil
9. cefaclor
10. trimethoprim with sulfamethoxazole
11. ciprofloxacin
12. azithromycin

Pharmacists may dispense prescriptions for these drugs when written by appropriately certified optometrists for treatment of the eyes.

Pharmacy Quality Assurance Programs

**SB 1339 (Figueroa)
Chapter 677,
Statutes of 2000**

B&PC 4125—requires all pharmacies to establish quality assurance programs designed to reduce the incidence of medication errors. Documents created in the course of these quality assurance programs are considered peer review documents and are not subject to discovery. The Board of Pharmacy is required to adopt regulations specifying the requirements of quality assurance programs before September 1, 2001.

Ambulance Restocking

**SB 1554 (Business
and Professions)
Chapter 836,
Statutes of 2000**

B&PC 4119—permits pharmacies to resupply ambulances with dangerous drugs and dangerous devices pursuant to an itemized written order from the emergency services provider. These dangerous drugs or dangerous devices are to be used exclusively in conjunction with ambulance services. Records regarding this activity must be retained in the pharmacy for three years.

Internet Pharmacy

**SB 1828 (Speier)
Chapter 681,
Statutes of 2000**

B&PC 4067—permits the Board to issue citations and fines up to \$25,000 per violation for dispensing a dangerous drug or dangerous device on the Internet without a valid prescription. This provision is designed to target Internet drug sales that do not require a prescription or provide a prescription via the Internet site without a good faith examination.

Medication Errors

**SB 1875 (Speier)
Chapter 816,
Statutes of 2000**

H&SC 1339.63—requires general acute care hospitals, special hospitals, and surgical clinics, as a condition of licensure, to adopt a formal plan to eliminate or substantially reduce medication-related errors. The bill requires each facility's plan to be provided to the State Department of Health Services by January 1, 2002, and to be implemented by January 1, 2005. This requirement is in addition to the quality assurance program required by SB 1339 as it pertains to the operation of the entire facility, not just the pharmacy. However, it is likely that the quality assurance program required by SB 1339 would be consistent with this requirement.

Medical Records

**SB 1903 (Speier)
Chapter 1066,
Statutes of 2000**

Civil Code 56.07, 56.10 and 56.11 and H&SC 12311—amend existing law to prohibit the disclosure of medical information between corporations and their subsidiaries and affiliates. The Gramm-Leach-Bliley Act passed by Congress permitted the merger of financial services companies with insurers, but did not prohibit the sharing of patient information between the parent company and its subsidiaries. This bill is intended to prohibit that sharing of information. In addition, the bill requires corporations and other organizations maintaining medical information to provide copies of patient records to patients at no charge. Lastly, the bill specifies new standards for the appropriate release of patient medical information and allows patients to insert written addenda into their medical records in response to any data the patient believes is incorrect or incomplete.

Answers to Questions on Triplicate Law Changes

Q. Changes in the amended Health & Safety Code 11164 (AB 2018) appear to make Schedule II prescription requirements less stringent than those of Schedules III and IV. Is that true?

A. That is true. The changes do require that fewer things on a Schedule II prescription be in the prescriber's handwriting than on prescriptions for Schedules III and IV controlled substances. For example, beginning in January 2001, on a Schedule II prescription only the prescriber's name must be in his or her handwriting. The date, patient's name and address, drug's name, quantity, strength and directions for use, the prescriber's address, type of licensure and DEA number may be typed or handwritten by the prescriber or his or her employee. And except for Schedule II prescriptions written for terminally ill patients pursuant to Health and Safety Code 11159.2, all other Schedule II prescriptions must still be written on a triplicate form.

However, for Schedules III and IV prescriptions, the date, prescriber's signature, patient's name, drug name, quantity and directions for use must be handwritten by the prescriber. See the table below:

Element	Schedule II	Schedule III & IV
Date		✓
Patient Name		✓
Patient Address		
Drug Name		✓
Quantity		✓
Directions		✓
Prescriber Name		
Prescriber Address		
Prescriber Telephone		
DEA Number		
License Classification		
Prescriber Signature	✓	✓

✓ — Elements of a prescription that must be written by the prescriber.



Q. Why can't I just follow the new Schedule II requirements when dispensing Schedules III and IV drugs?

A. Under both federal and state law, prescription requirements for Schedules III and IV drugs are treated separately from those of Schedule II drugs. The new changes for dispensing apply only to Schedule II drugs. Although there is an inconsistency between the new Schedule II dispensing requirements and those of Schedules III and IV drugs, the requirements for Schedules III and IV prescriptions are unchanged and will continue to be enforced.

Q. Do changes approved by the prescriber require a new triplicate form to be issued?

A. No. After consulting with the prescriber and receiving approval for a change on a Schedule II prescription, the pharmacist may dispense the prescription with the changes. There are several options for documenting the changes authorized by the prescriber:

1. The pharmacist may fax a photocopy of the triplicate prescription (with the changes added to the photocopy) to the prescriber for his or her signature, and have the prescriber sign the faxed photocopy and fax or mail it back to the pharmacy;
2. The prescriber may fax or mail to the pharmacist the prescription, rewritten on an ordinary prescription form and containing the corrections and prescriber's signature, or
3. The prescriber may correct his/her copy (adding a second signature for the corrections) of the triplicate and fax or mail it to the pharmacy.

Regardless of which option is chosen from the above list, the prescriber must fax or mail the correction to the pharmacist within seven days of the prescription being dispensed. The pharmacist must attach the correction document (one of the above) to the triplicate prescription form retained by the pharmacy.

It is particularly important for pharmacists to document their contact with the prescriber and to retain that record and any hard copy documents that are faxed to the prescriber.

Q. Since corrections to triplicate prescription forms can now be faxed, can the triplicate be faxed to a pharmacy for dispensing instead of sending the triplicate itself?

- A. No. The law still requires that the pharmacist be in possession of a triplicate form before dispensing the prescription. Pharmacies must still forward the original triplicate form to the

Department of Justice and comply with CURES reporting requirements.

Q. The prescriber did not indicate the strength of the Schedule II drug on the triplicate prescription. Is it legal for the pharmacist to check with the prescriber for the appropriate strength and dispense that to the patient?

- A. Yes. Section 11164 of the Health & Safety Code permits a pharmacist to dispense a prescription with an error or errors (the absence of a strength would be an error) provided the pharmacist first consults with the prescriber and the prescriber sends a correction.

Q. What changes are considered "corrections" versus an incomplete triplicate that must be returned to the prescriber?

- A. Schedule II prescriptions must be returned to the prescriber if they lack any of the following:

- Issue date,
- Prescriber's name,
- Prescriber's signature,
- Patient's name, or
- Name of the drug to be dispensed.

Other errors are subject to correction through consulting with the prescriber and the subsequent submission of a written correction by the prescriber.



Rx for Good Practice

In day-to-day pharmacy practice, unusual situations sometimes occur, generating questions. So to help our licensees with questions whose answers may or may not be found in the pharmacy law book, "Rx for Good Practice" will be featured in each issue of *The Script*. If you have a question you would like to see answered in this column, please fax your question to *The Script* at (916) 327-6308 or e-mail it to the editor at hope_tamraz@dca.ca.gov.

Q. Can a California pharmacist fill a prescription written by a military-based physician, even though the prescribing physician is not licensed in California?

- A. Military dependents often obtain prescriptions from their military base facilities but take them to California retail pharmacies for filling. In many cases the physicians are not licensed in California. Section 1301.13 of Title 21, Code of Federal Regulations (21 CFR) allows individual practitioners who practice in federal, state, or local hospitals or other institutions (when engaging in their official duties) to administer, dispense, or prescribe controlled substances under the Drug Enforcement Administration (DEA) registration of the government institution in lieu of being individually registered.

The guidelines for dispensing prescriptions from out-of-state prescribers employed at federal medical institutions are:

- Schedule II controlled substance prescriptions must be written on Bureau of Narcotics Enforcement triplicate forms and contain:
 - (a) The federal medical institution's DEA-issued number and the individual prescriber's state license number preceded by the two-character state alpha code (e.g., AB 1234567, NV 654321) written or printed in the upper right corner of the form, directly above the triplicate serial number.
 - (b) When space permits, the facility name will be printed below the prescriber's name in the upper left corner of the form, directly above the facility address.
 - (c) "GOVERNMENT FACILITY EXEMPT PRESCRIBER" will be printed just below the quantity boxes on the face of every GFEP prescription issued.
 - (d) The "NOT VALID AFTER" date at the bottom of the form will reflect a two-year period (rather than five years).

Requests for additional information or further clarification of the instructions regarding Schedule II controlled substance prescriptions should be directed to the BNE at (916) 227-4050 or (916) 227-4051.

- **Schedule III, IV, and V prescriptions** must contain the federal institution's registration number and an internal identifying code number for the prescriber pursuant to section 1301.24(c)(5) of the CFR. That code number (can be numbers, letters, or a combination) will be a suffix to the facility's DEA number and preceded by a hyphen (e.g., ZS 1234567-PP8910). Additionally, section 1301.21(c)(6) 21 CFR directs such facilities to have available at all times a current list of the prescribers and their internal codes. Civilian pharmacists may contact the facility to verify the prescriber's identity.

Q. By March 31, 2001, all PICs are to have completed a new pharmacy self-assessment form. Will the Board be mailing the forms out to each pharmacy?

- A. Recent changes to pharmacy law necessitate appropriate changes to the self-assessment forms, and these changes require regulatory action. Once the regulation is adopted, the Board will publish the new forms on its website and mail the new form to each pharmacy. Among the proposed changes is a new due date for completing these forms, but until the new forms are ready, PICs will continue to complete the current form by March 31, 2001. If you need a copy of the form, you may request it from the Board or download it from the Board's website (www.pharmacy.ca.gov).



Live Scan fingerprinting is here!

For criminal record checks, applicants for registration with the Board traditionally have been required to submit their fingerprints on cards. However, beginning January 1, 2001, all fingerprinting for the Board of Pharmacy must be submitted electronically via “Live Scan” rather than on hard copy fingerprint cards.

The Board previously secured criminal record checks through the California Department of Justice (DOJ) and in some instances, the FBI. These checks could sometimes take as many as 12 weeks for processing. Now, with the electronic transmission and speedy processing, the Board will be requiring criminal record checks by both the DOJ and the FBI for all applicants.

What is Live Scan fingerprinting?

Live Scan is inkless electronic fingerprinting, and the digitized fingerprints and personal descriptor information are electronically transmitted to the DOJ and the FBI for completion of criminal record checks. This process takes only seconds, whereas previously, mailing the cards to the Board for forwarding to the DOJ and the FBI often took a week or more. Additional time is saved because by using this system, the DOJ hopes to process up to 95% of

the prints within three days, as opposed to the six to eight weeks it previously took to process the fingerprint cards.

Where are the Live Scan sites located?

There are more than 130 Live Scan sites throughout the state, and applicants should contact their local police or sheriff’s department for the nearest site available to the general public. Also, an up-to-date site list can be found at <http://caag.state.ca.us/app/contact.pdf>.

Who will be affected by this new system?

This new system will impact not only new applicants for Board licensure or registration, but also those who have already been fingerprinted for the Board and are applying for a new registration. For example, pharmacy interns applying to take the Board’s pharmacist licensure exam or technicians applying for intern registration will be required to be fingerprinted again, using the Live Scan system. Additionally, applications for new pharmacy license numbers (change of permit, ownership, or location) will require applicants to have a federal criminal check except for the pharmacists-in-charge (unless they are also owners or officers).

All Board application packets mailed to locations in California will contain the Board’s “Request for Live Scan Service” form and instructions for its preparation. The form contains special codes to ensure prompt notification of the criminal record check results, and for that reason, **applicants must use Board forms ONLY**. Applicants must complete the form and have fingerprints scanned before submitting their application to the Board. If you presently have an application that will not be submitted until after January 1, please call the Board at (916) 445-5014 and press option 2 (the application request line) and ask for the “Request for Live Scan Service” form and instructions.



Live Scan*Continued from Page 11*

Exceptions to these procedures are out-of-state applicants who will still submit Board-issued cards with rolled fingerprints and a fee of \$66 (\$42 for the expedited DOJ criminal record check and \$24 for the FBI criminal record check).

What does the Live Scan fingerprinting process cost?

The cost for electronic fingerprinting is determined by the local Live Scan agency and will range from about \$5-\$20. In addition, the applicant will be required to pay the processing fee at the time of fingerprinting. The fee is \$56 (\$32 for the DOJ criminal record check and \$24 for the FBI criminal record check).

You may contact the Board if you have questions regarding Live Scan.



Before hiring...

pharmacists, pharmacy interns or pharmacy technicians, remember that to function in those positions, the applicants **MUST** hold current registration with the California Board of Pharmacy. It is a violation of law for those individuals to work in California pharmacies without proper California registration (B & PC 4030, 4115(e)(1) and 4036). If an applicant for employment is hired and works without proper licensure, not only is that individual in violation, but also the pharmacist-in-charge and other responsible persons who permit the violation.

The only exception to this rule is that pharmacists who have current licensure in other states may be employed at federal institutions within California.

Before hiring any employee whose position requires Board licensure or registration by the Board, verify that licensure or registration at www.pharmacy.ca.gov or by calling the Board at (916) 445-5014.

Pharmacy Board meetings are open to the public

In accordance with its Strategic Plan, the Board formed committees to address issues related to meeting the plan's objectives. To share the various committee goals, activities and accomplishments with the public, a portion of each Board meeting will be devoted to one of the committees and open for public comment.

The Board meeting dates and sites for 2001 are:

- ◆ January 24-25, 2001
Sheraton Gateway Hotel LAX
6101 West Century Blvd.
Los Angeles CA 90045
(310) 642-1111
- The Public Communication & Education Committee will present a report on its current and proposed activities at this meeting.
- ◆ April 25-26, 2001
Department of Consumer Affairs
400 R Street, 1st Floor Hearing Room
Sacramento CA 95814
Contact: Candy Place (916) 445-5014 Ext. 4006
- ◆ July 25-26, 2001
San Diego
To be determined
- ◆ October 17-18, 2001
San Francisco CA
To be determined

Agendas with meeting times, locations and information regarding Board committee meetings may be obtained by calling the Board at (916) 445-5014.





Law Update

This article contains additions and amendments to Chapter 9, Division 2 of the Business & Professions Code and Division 10, Chapter 4 of the Health & Safety Code. It also contains additions to Chapter 17, Title 16 of the California Code of Regulations and Division 1, Part 2.6 of the Civil Code. Italics indicates new text and *** indicates that text has been deleted. For your convenience, these sections are included here so that they may be cut out and saved until the next publication of the Pharmacy Law.

Business & Professions Code

3041 (Amended and included here in its entirety because it is not in the Pharmacy Law)

(a) The practice of optometry *includes the prevention and diagnosis of disorders and dysfunctions of the visual system, and the treatment and management of certain disorders and dysfunctions of the visual system, as well as the provision of rehabilitative optometric services*, and is the doing of any or all of the following:

(1) The examination of the human eye or eyes, or its or their

appendages, and the analysis of the human vision system, either subjectively or objectively.

(2) The determination of the powers or range of human vision and the accommodative and refractive states of the human eye or eyes, including the scope of its or their functions and general condition.

(3) The prescribing or directing the use of, or using, any optical device in connection with ocular exercises, visual training, vision training, or orthoptics.

(4) The prescribing of contact and spectacle lenses for, or the fitting or adaptation of contact and spectacle lenses to, the human eye, including lenses which may be classified as drugs or devices by any law of the United States or of this state.

(5) The use of topical pharmaceutical agents for the sole purpose of the examination of the human eye or eyes for any disease or pathological condition. The topical pharmaceutical agents shall include mydriatics, cycloplegics, anesthetics, and agents for the reversal of mydriasis.

See Law Update, Page 14

Law Update*Continued from Page 13*

(b) (1) An optometrist who is certified to use therapeutic pharmaceutical agents, pursuant to Section 3041.3, may also diagnose and exclusively treat the human eye or eyes, or any of its appendages, for all of the following conditions***:

(A)*** Through medical treatment, infections of the anterior segment and adnexa, excluding the lacrimal gland, the lacrimal drainage system and the sclera. Nothing in this section shall authorize any optometrist to treat a person with AIDS for ocular infections.

(B) ***Ocular allergies of the anterior segment and adnexa.

(C) ***Ocular inflammation, nonsurgical in cause, limited to inflammation resulting from traumatic iritis, peripheral corneal inflammatory keratitis, episcleritis, and unilateral nonrecurrent nongranulomatous idiopathic iritis in patients over the age of 18.

Unilateral nongranulomatous idiopathic iritis recurring within one year of the initial occurrence shall be referred to an ophthalmologist. An optometrist shall consult with an ophthalmologist if a patient has a recurrent case of episcleritis within one year of the initial occurrence. An optometrist shall consult with an ophthalmologist if a patient has a recurrent case of peripheral corneal inflammatory keratitis within one year of the initial occurrence.

(D) Traumatic or recurrent conjunctival or corneal abrasions and erosions.

(E) Corneal surface disease and dry eyes.

(F) Ocular pain, not related to surgery, associated with conditions optometrists are authorized to treat.

(G) Pursuant to subdivision (f), primary open angle glaucoma in patients over the age of 18.

(2) *For purposes of this section, "treat" means the use of therapeutic pharmaceutical agents, as described in subdivision (c), and the procedures described in subdivision (e).*

(c) ****In diagnosing and treating the conditions listed in subdivision (b), an optometrist certified to use therapeutic pharmaceutical agents pursuant to Section 3041.3, may use all of the following therapeutic pharmaceutical agents exclusively:*

(1) All of the topical pharmaceutical agents listed in paragraph (5) of subdivision (a) as well as topical miotics for diagnostic purposes.

(2) Topical lubricants.

(3) *Topical antiallergy agents. In using topical steroid medication for the treatment of ocular allergies, an optometrist shall do the following:*

(A) *Consult with an ophthalmologist if the patient's condition worsens 72 hours after diagnosis.*

(B) *Consult with an ophthalmologist if the inflammation is still present three weeks after diagnosis.*

(C) *Refer the patient to an ophthalmologist if the patient is still on the medication six weeks after diagnosis.*

(D) *Refer the patient to an ophthalmologist if the patient's condition recurs within three months.*

(4) Topical anti-inflammatories. In using topical steroid medication for:

(A) Unilateral nonrecurrent nongranulomatous idiopathic iritis or episcleritis, an optometrist shall consult with an ophthalmologist if the patient's condition worsens 72 hours after the diagnosis, or if the patient's condition has not resolved three weeks after diagnosis. If the patient is still receiving medication for these conditions six weeks after diagnosis, the optometrist shall refer the patient to an ophthalmologist.

(B) Peripheral corneal inflammatory keratitis, excluding Moorens and Terriens diseases, an optometrist shall consult with an ophthalmologist if the patient's condition worsens 48 hours after diagnosis. If the patient is still receiving the medication two weeks after diagnosis, the optometrist shall refer the patient to an ophthalmologist.

(C) Traumatic iritis, an optometrist shall consult with an ophthalmologist if the patient's condition worsens 72 hours after diagnosis and shall refer the patient to an ophthalmologist if the patient's condition has not resolved one week after diagnosis.

(5) Topical antibiotic agents.

(6) Topical hyperosmotics.

(7) Topical anti-glaucoma agents pursuant to the certification process defined in subdivision (f).

(A) The optometrist shall not use more than two concurrent topical medications in treating the patient for primary open angle glaucoma. A single combination medication that contains two pharmacological agents shall be considered as two medications.

(B) The optometrist shall refer the patient to an ophthalmologist if requested by the patient, if treatment goals are not achieved with the use of two topical medications or if indications of narrow angle or secondary glaucoma develop.

(C) *If the glaucoma patient also has diabetes, the optometrist shall consult in writing with the physician treating the patient's diabetes in developing the glaucoma treatment plan and shall notify the physician in writing of any changes in the patient's glaucoma medication. The physician shall provide written confirmation of such consultations and notifications.*

(8) Nonprescription medications used for the rational treatment of an ocular disorder.

(9) Oral antihistamines. In using oral antihistamines for the treatment of ocular allergies, the optometrist shall refer the patient to an ophthalmologist if the patient's condition has not resolved two weeks after diagnosis.

(10) Prescription oral nonsteroidal anti-inflammatory agents. The agents shall be limited to three days' use. If the patient's condition has not resolved three days after diagnosis, the optometrist shall refer the patient to an ophthalmologist.

(11) The following oral antibiotics for medical treatment as set forth in subparagraph (A) of paragraph (1) of subdivision (b): tetracyclines, dicloxacillin, amoxicillin, amoxicillin with clavulanate, erythromycin, clarythromycin, cephalexin, cephadroxil, cefaclor, trimethoprim with sulfamethoxazole, ciprofloxacin, and azithromycin. The use of azithromycin shall be limited to the treatment of eyelid infections and chlamydial disease manifesting in the eyes.

(A) If the patient has been diagnosed with a central corneal ulcer and the condition has not improved 24 hours after diagnosis, the optometrist shall consult with an ophthalmologist. If the central corneal ulcer has not improved 48 hours after diagnosis, the optometrist shall refer the patient to an ophthalmologist. If the patient is still receiving antibiotics 10 days after diagnosis, the optometrist shall refer the patient to an ophthalmologist.

(B) If the patient has been diagnosed with preseptal cellulitis or dacryocystitis and the condition has not improved 72 hours after diagnosis, the optometrist shall refer the patient to an ophthalmologist. If a patient with preseptal cellulitis or dacryocystitis is still receiving oral antibiotics 10 days after diagnosis, the optometrist shall refer the patient to an ophthalmologist.

(C) If the patient has been diagnosed with blepharitis and the patient's condition does not improve after six weeks of treatment, the optometrist shall consult with an ophthalmologist.

(D) For the medical treatment of all other medical conditions as set forth in subparagraph (A) of paragraph (1) of subdivision (b), if the patient's condition worsens 72 hours after diagnosis, the optometrist shall consult with an ophthalmologist. If the patient's condition has not resolved 10 days after diagnosis, the optometrist shall refer the patient to an ophthalmologist.

(12) Topical antiviral medication and oral acyclovir for the medical treatment of the following: herpes simplex viral keratitis, herpes simplex viral conjunctivitis and periocular herpes simplex viral dermatitis; and varicella zoster viral keratitis, varicella zoster viral conjunctivitis and periocular varicella zoster viral dermatitis.

(A) If the patient has been diagnosed with herpes simplex keratitis or varicella zoster viral keratitis and the patient's condition has not improved seven days after diagnosis, the optometrist shall refer the patient to an ophthalmologist. If a patient's condition has not resolved three weeks after diagnosis, the optometrist shall refer the patient to an ophthalmologist.

(B) If the patient has been diagnosed with herpes simplex viral conjunctivitis, herpes simplex viral dermatitis, varicella zoster viral conjunctivitis or varicella zoster viral dermatitis, and if the patient's condition worsens seven days after diagnosis, the optometrist shall consult with an ophthalmologist. If the

patient's condition has not resolved three weeks after diagnosis, the optometrist shall refer the patient to an ophthalmologist.

(C) In all cases, the use of topical antiviral medication shall be limited to three weeks, and the use of oral acyclovir shall be limited to 10 days.

(13) Oral analgesics that are not controlled substances.

(14) Codeine with compounds and hydrocodone with compounds as listed in the California Uniform Controlled Substances Act (Section 11000 of the Health and Safety Code et seq.) and the United States Uniform Controlled Substances Act (21 U.S.C. Sec. 801 et seq.). The use of these agents shall be limited to three days, with a referral to an ophthalmologist if the pain persists.

*(d) ***In any case where this chapter requires that an optometrist consult with an ophthalmologist, the optometrist shall maintain a written record in the patient's file of the information provided to the ophthalmologist, the ophthalmologist's response and any other relevant information. Upon the consulting ophthalmologist's request, the optometrist shall furnish a copy of the record to the ophthalmologist.*

(e) An optometrist who is certified to use therapeutic pharmaceutical agents pursuant to Section 3041.3 may also perform all of the following:

(1) Mechanical epilation.

(2) Ordering of smears, cultures, sensitivities, complete blood count, mycobacterial culture, acid fast stain, and urinalysis***.

*(3) ***Punctal occlusion by plugs, excluding laser, cautery, diathermy, cryotherapy, or other means constituting surgery as defined in this chapter.*

(4) The prescription of therapeutic contact lenses.

(5) Removal of ***foreign bodies of the cornea, eyelid, and conjunctiva. *Corneal foreign bodies shall be nonperforating, be no deeper than the anterior stroma, and require no surgical repair upon removal. Within the central three millimeters of the cornea, the use of sharp instruments is prohibited.*

(6) ***For patients over the age of 12 years, lacrimal irrigation and dilation, excluding probing of the nasal lacrimal tract. The State Board of Optometry shall certify an optometrist to perform this procedure after completing 10 of the procedures under the supervision of an ophthalmologist as confirmed by the ophthalmologist.

(7) No injections other than the use of an auto-injector to counter anaphylaxis.

*(f) ***The State Board of Optometry shall grant a certificate to an optometrist certified pursuant to Section 3041.3 for the treatment of primary open angle glaucoma in patients over the*

Law Update*Continued from Page 15*

age of 18 only after the optometrist meets the following requirements:

(1) Satisfactory completion of a didactic course of not less than 24 hours in the diagnosis, pharmacological and other treatment and management of glaucoma. The 24-hour glaucoma curriculum shall be developed by an accredited California school of optometry. Any applicant who graduated from an accredited California school of optometry on or after May 1, 2000, shall be exempt from the 24-hour didactic course requirement contained in this paragraph.

(2) After completion of the requirement contained in paragraph (1), collaborative treatment of 50 glaucoma patients for a period of two years for each patient under the following terms:

(A) After the optometrist makes a provisional diagnosis of glaucoma, the optometrist and the patient shall identify a collaborating ophthalmologist.

(B) The optometrist shall develop a treatment plan that considers for each patient target intraocular pressures, optic nerve appearance and visual field testing for each eye, and an initial proposal for therapy.

(C) The optometrist shall transmit relevant information from the examination and history taken of the patient along with the treatment plan to the collaborating ophthalmologist. The collaborating ophthalmologist shall confirm or refute the glaucoma diagnosis within 30 days. To accomplish this, the collaborating ophthalmologist shall perform a physical examination of the patient.

(D) Once the collaborating ophthalmologist confirms the diagnosis and approves the treatment plan in writing, the optometrist may begin treatment.

(E) The optometrist shall use no more than two concurrent topical medications in treating the patient for glaucoma. A single combination medication that contains two pharmacologic agents shall be considered as two medications. The optometrist shall notify the collaborating ophthalmologist in writing if there is any change in the medication used to treat the patient for glaucoma.

(F) Annually after commencing treatment, the optometrist shall provide a written report to the collaborating ophthalmologist about the achievement of goals contained in the treatment plan. The collaborating ophthalmologist shall acknowledge receipt of the report in writing to the optometrist within 10 days.

(G) The optometrist shall refer the patient to an ophthalmologist if requested by the patient, if treatment goals are not achieved with the use of two topical medications, or if indications of secondary glaucoma develop. At his or her discretion, the collaborating ophthalmologist may periodically examine the patient.

(H) If the glaucoma patient also has diabetes, the optometrist shall consult in writing with the physician treating the patient's

diabetes in preparation of the treatment plan and shall notify the physician in writing if there is any change in the patient's glaucoma medication.

The physician shall provide written confirmation of the consultations and notifications.

(I) The optometrist shall provide the following information to the patient in writing: nature of the working or suspected diagnosis, consultation evaluation by a collaborating ophthalmologist, treatment plan goals, expected follow-up care, and a description of the referral requirements. The document containing the information shall be signed and dated by both the optometrist and the ophthalmologist and maintained in their files.

(3) When the requirements contained in paragraphs (1) and (2) have been satisfied, the optometrist shall submit proof of completion to the State Board of Optometry and apply for a certificate to treat primary open angle glaucoma. That proof shall include corroborating information from the collaborating ophthalmologist. If the ophthalmologist fails to respond within 60 days of a request for information from the State Board of Optometry, the board may act on the optometrist's application without that corroborating information.

(4) After an optometrist has treated a total of 50 patients for a period of two years each and has received certification from the State Board of Optometry, the optometrist may treat the original 50 collaboratively treated patients independently, with the written consent of the patient. However, any glaucoma patients seen by the optometrist before the two-year period has expired for each of the 50 patients shall be treated under the collaboration protocols described in this section.

(g) ***Notwithstanding any other provision of law, an optometrist shall not treat children under one year of age with therapeutic pharmaceutical agents.

(h) ***Any dispensing of a therapeutic pharmaceutical agent by an optometrist shall be without charge.

(i) Notwithstanding any other provision of law, the practice of optometry does not include performing surgery. "Surgery" means any procedure in which human tissue is cut, altered, or otherwise infiltrated by mechanical or laser means in a manner not specifically authorized by this act. Nothing in the act amending this section shall limit an optometrist's authority, as it existed prior to the effective date of the act amending this section, to utilize diagnostic laser and ultrasound technology.

(j) *All collaborations, consultations, and referrals made by an optometrist pursuant to this section shall be to an ophthalmologist located geographically appropriate to the patient.*

4019 (Amended)

An "order," entered on the chart or medical record of a patient registered in a hospital or a patient under emergency treatment in the hospital, by or on the order of a practitioner authorized by

law to prescribe drugs, shall be authorization for the administration of the drug from hospital floor or ward stocks furnished by the hospital pharmacy or under licensure granted under Section 4056, and shall be considered to be a prescription if the medication is to be furnished directly to the patient by the hospital pharmacy or another pharmacy furnishing prescribed drugs for hospital patients; provided that the chart or medical record of the patient contains all of the information required by Sections 4040 and 4070 and the order is signed by the practitioner authorized by law to prescribe drugs, if he or she is present when the drugs are given***. *If he or she is not present when the drugs are given, the order shall be signed either by the attending physician responsible for the patient's care at the time the drugs are given to the patient or by the practitioner who ordered the drugs for the patient on the practitioner's next visit to the hospital.*

4067 (New)

(a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars (\$25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars (\$25,000) per occurrence.

(c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).

(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

(e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.

4070 (Amended)

(a) Except as provided in Section 4019 and subdivision (b), an oral or an electronic data transmission prescription as defined in subdivision (c) of Section 4040 shall as soon as practicable be

reduced to writing by the pharmacist and shall be filled by, or under the direction of, the pharmacist. The pharmacist need not reduce to writing the address, telephone number, license classification, federal registry number of the prescriber or the address of the patient or patients if the information is readily retrievable in the pharmacy.

(b) A pharmacy receiving an electronic transmission prescription shall not be required to reduce that prescription to writing or to hard copy form if, for three years from the last date of furnishing pursuant to that prescription or order, the pharmacy is able, upon request by the board, to immediately produce a hard copy report that includes for each date of dispensing of a dangerous drug or dangerous device pursuant to that prescription or order: (1) all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040, and (2) the name or identifier of the pharmacist who dispensed the dangerous drug or dangerous device. This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code.

(c) If only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's computer system shall not permit the received information or the dangerous drug or dangerous device dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law once the information has been received by the pharmacy and once the dangerous drug or dangerous device has been dispensed. Once a dangerous drug or dangerous device has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(d) Nothing in this section shall impair the requirement to have an electronically transmitted prescription transmitted only to the pharmacy of the patient's choice or to have a written prescription. This requirement shall not apply to orders for medications to be administered in an acute care hospital.

4071.1 (New)

(a) A prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in Section 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. For purposes of this section, a "prescriber's authorized agent" is a person licensed or registered under Division 2 (commencing with Section 500). This subdivision shall not apply to prescriptions for controlled

Law Update

Continued from Page 17

substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code.

(b) Nothing in this section shall reduce the existing authority of other hospital personnel to enter medication orders or prescription orders into a hospital's computer.

(c) No dangerous drug or dangerous device shall be dispensed pursuant to a prescription that has been electronically entered into a pharmacy's computer without the prior approval of a pharmacist.

4119 (Amended)

(a) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Health Services set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility's patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to 24.

(b) Notwithstanding any other provision of law, a pharmacy may furnish a dangerous drug or a dangerous device to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency, if all of the following are met:

(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction with services provided in an ambulance, or other approved emergency medical services service provider, that provides prehospital emergency medical services.

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician's scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.

(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.

(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years.

The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances Act.

4125 (New)

(a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

(b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.

(c) This section shall become operative on January 1, 2002.

SEC. 2. The California State Board of Pharmacy shall adopt regulations on or before September 1, 2001, specifying the requirements and implementation of quality assurance programs established pursuant to Section 4125 of the Business and Professions Code.

4139 (New)

(a) Licenses to conduct a medical device retailer issued or renewed by the California State Board of Pharmacy prior to July 1, 2001, shall remain valid until one year after the date of the issuance or renewal of the license. On or after July 1, 2001, the California State Board of Pharmacy shall not issue or renew a medical device retailer license. Thereafter, entities seeking licensure as a home medical device retail facility shall apply to the State Department of Health Services.

(b) This section shall remain in effect only until July 1, 2002,

and as of January 1, 2003, is repealed, unless a statute, which is enacted before January 1, 2003, deletes or extends that date.

Health & Safety Code

1339.63 (New and included here because it is not in the Pharmacy Law) (a) (1) *As a condition of licensure under this division, every general acute care hospital, as defined in subdivision (a) of Section 1250, special hospital, as defined in subdivision (f) of Section 1250, and surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204, shall adopt a formal plan to eliminate or substantially reduce medication-related errors. With the exception of small and rural hospitals, as defined in Section 124840, this plan shall include technology implementation, such as, but not limited to, computerized physician order entry or other technology that, based upon independent, expert scientific advice and data, has been shown effective in eliminating or substantially reducing medication-related errors.*

(2) Each facility's plan shall be provided to the State Department of Health Services no later than January 1, 2002. Within 90 days after submitting a plan, the department shall either approve the plan, or return it to the facility with comments and suggestions for improvement. The facility shall revise and resubmit the plan within 90 days after receiving it from the department. The department shall provide final written approval within 90 days after resubmission, but in no event later than January 1, 2003. The plan shall be implemented on or before January 1, 2005.

(b) Any of the following facilities that is in the process of constructing a new structure or retrofitting an existing structure for the purposes of complying with seismic safety requirements shall be exempt from implementing a plan by January 1, 2005:

(1) General acute care hospitals, as defined in subdivision (a) of Section 1250.

(2) Special hospitals, as defined in subdivision (f) of Section 1250.

(3) Surgical clinics, as defined in paragraph (1) of subdivision (b) of Section 1204.

(c) The implementation date for facilities that are in the process of constructing a new structure or retrofitting an existing structure shall be six months after the date of completion of all retrofitting or new construction. The exemption and new implementation date specified in this paragraph shall apply to those facilities that have construction plans and financing for these projects in place no later than July 1, 2002.

(d) *For purposes of this chapter, a "medication-related error" means any preventable medication-related event that adversely affects a patient in a facility listed in subdivision (a), and that is related to professional practice, or health care products, procedures, and systems, including, but not limited to, prescribing, prescription order communications, product labeling,*

packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

11026 (Amended)

"Practitioner" means any of the following:

(a) A physician, dentist, veterinarian, podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, or a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code.

(b) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

(c) A scientific investigator, or other person licensed, registered, or otherwise permitted, to distribute, dispense, conduct research with respect to, or administer, a controlled substance in the course of professional practice or research in this state.

11056 (Amended to include the following as Schedule III) ...

(h) *Hallucinogenic substances. Any of the following hallucinogenic substances: dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the federal Food and Drug Administration.*

11150 (Amended)

No person other than a physician, dentist, podiatrist, or veterinarian, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

Law Update*Continued from Page 19***11161 (Amended)**

(a) Prescription blanks shall be issued by the Department of Justice in serially numbered groups of not more than 100 forms each in triplicate *unless a practitioner orally, electronically, or in writing requests a larger amount*, and shall be furnished to any practitioner authorized to write a prescription for controlled substances classified in Schedule II. The Department of Justice may charge a fee for the prescription blanks sufficient to reimburse the department for the actual costs associated with the preparation, processing, and filing of any forms issued pursuant to this section. The prescription blanks shall not be transferable.

***Any person possessing a triplicate prescription blank otherwise than as provided in this section is guilty of a misdemeanor...

11163 (Repealed)**11164 (Amended)**

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense such a prescription unless it complies with the requirements of this section.

(a) The signature on each prescription for a controlled substance classified in Schedule II shall be wholly written in ink or indelible pencil in the handwriting of the prescriber upon the official prescription form issued by the Department of Justice. Each prescription shall be prepared in triplicate, signed by the prescriber, and shall contain, *either typewritten or handwritten by the physician or his or her employee*, the date, name, and address of the person for whom the controlled substance is prescribed, the name, quantity, and strength of the controlled substance prescribed, directions for use, and the address, category of professional licensure, and the federal controlled substance registration number of the prescriber. The original and duplicate of the prescription shall be delivered to the pharmacist filling the prescription. The duplicate shall be retained by the pharmacist and the original, properly endorsed by the pharmacist with the name and address of the pharmacy, the pharmacy's state license number, the date the prescription was filled and the signature of the pharmacist, shall be transmitted to the Department of Justice at the end of the month in which the prescription was filled. Upon receipt of an incompletely prepared official prescription form of the Department of Justice, the pharmacist may enter on the face of the prescription the address of the patient. *A pharmacist may fill a prescription for a controlled substance classified in Schedule II containing an error or errors, if the pharmacist notifies the prescriber of the error or errors and the prescriber approves any correction. The prescriber shall fax or mail a corrected prescription to the pharmacist within seven days of the prescription being dispensed. ...*

11164.5 (New)

(a) Notwithstanding Section 11164, with the approval of the California State Board of Pharmacy and the Department of Justice, a pharmacy or hospital may receive electronic data

transmission prescriptions or computer entry prescriptions or orders as specified in Section 4071.1 of the Business and Professions Code, for controlled substances in Schedule II, III, IV, or V if authorized by federal law and in accordance with regulations promulgated by the Drug Enforcement Administration. The California State Board of Pharmacy shall maintain a list of all requests and approvals granted pursuant to this subdivision.

(b) Notwithstanding Section 11164, if approved pursuant to subdivision (a), a pharmacy or hospital receiving an electronic transmission prescription or a computer entry prescription or order for a controlled substance classified in Schedule II, III, IV, or V shall not be required to reduce that prescription or order to writing or to hard copy form, if for three years from the last day of dispensing that prescription, the pharmacy or hospital is able, upon request of the board or the Department of Justice, to immediately produce a hard copy report that includes for each date of dispensing of a controlled substance in Schedules II, III, IV, and V pursuant to the prescription all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040 of the Business and Professions Code and the name or identifier of the pharmacist who dispensed the controlled substance.

(c) Notwithstanding Section 11164, if only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's or hospital's computer system shall not permit the received information or the controlled substance dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.

(d) Nothing in this section shall be construed to exempt any pharmacy or hospital dispensing Schedule II controlled substances pursuant to electronic transmission prescriptions from existing reporting requirements.

11210 (Amended)

A physician, surgeon, dentist, veterinarian, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of

Chapter 3 of Part 3 of Division 107, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code may prescribe for, furnish to, or administer controlled substances to his or her patient when the patient is suffering from a disease, ailment, injury, or infirmities attendant upon old age, other than addiction to a controlled substance.

The physician, surgeon, dentist, veterinarian, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code shall prescribe, furnish, or administer controlled substances only when in good faith he or she believes the disease, ailment, injury, or infirmity requires the treatment.

The physician, surgeon, dentist, veterinarian, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code shall prescribe, furnish, or administer controlled substances only in the quantity and for the length of time as are reasonably necessary.

12311 (New)

(a) Any adult patient who inspects his or her patient records pursuant to Section 123110 shall have the right to provide to the health care provider a written addendum with respect to any item or statement in his or her records that the patient believes to be incomplete or incorrect. The addendum shall be limited to 250 words per alleged incomplete or incorrect item in the patient's record and shall clearly indicate in writing that the patient wishes the addendum to be made a part of his or her record.

(b) The health care provider shall attach the addendum to the patient's records and shall include that addendum whenever the health care provider makes a disclosure of the allegedly incomplete or incorrect portion of patient's records to any third party.

(c) The receipt of information in a patient's addendum which contains defamatory or otherwise unlawful language, and the inclusion of this information in the patient's records, in accordance with subdivision (b), shall not, in and of itself, subject the health care provider to liability in any civil, criminal, administrative, or other proceeding.

(d) Subdivision (f) of Section 123110 and Section 123120 shall be applicable with respect to any violation of this section by a health care provider.

109948 (New)

(a) "Home medical device retail facility" is an area, place, or premises, other than a licensed pharmacy, in and from which prescription devices, home medical devices, or home medical device services are sold, fitted, or dispensed pursuant to prescription. "Home medical device retail facility" includes, but is not limited to, any area or place in which prescription devices, home medical devices, or home medical device services are stored, possessed, prepared, manufactured, or repackaged, and from which the prescription devices, home medical devices, and home medical device services are furnished, sold, or dispensed at retail.

(b) "Home medical device retail facility" shall not include any area in a facility licensed by the department where floor supplies, ward supplies, operating room supplies, or emergency room supplies of prescription devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility. (c) "Home medical device retail facility" shall not include any area of a home health agency licensed under Chapter 8 (commencing with Section 1725) of, or a hospice licensed under Chapter 8.5 (commencing with Section 1745) of Division 2 where the supplies specified in subdivision (c) of Section 4057 of the Business and Professions Code are stored or possessed solely for treatment of patients by a licensed home health agency or licensed hospice, as long as all prescription devices are furnished to these patients only upon the prescription or order of health care practitioners authorized to prescribe or order home medical devices or who use home medical devices or who use home medical devices to treat their patients.

109948.1 (New)

(a) "Home medical device services" means the delivery, installation, maintenance, replacement of, or instruction in the use of, home medical devices used by a sick or disabled individual to allow the individual to be maintained in a residence.

(b) "Home medical device" means a device intended for use in a home care setting including, but not limited to, all of the following:

- (1) Oxygen and oxygen delivery systems.
- (2) Ventilators.
- (3) Continuous Positive Airway Pressure devices (CPAP).
- (4) Respiratory disease management devices.
- (5) Hospital beds and commodes.
- (6) Electronic and computer driven wheelchairs and seating systems.
- (7) Apnea monitors.

Law Update

Continued from Page 21

- (8) *Low air loss continuous pressure management devices.*
- (9) *Transcutaneous Electrical Nerve Stimulator (TENS) units.*
- (10) *Prescription devices.*
- (11) *Medical gases for human consumption.*
- (12) *Disposable medical supplies including, but not limited to, incontinence supplies as defined in Section 14125.1 of the Welfare and Institutions Code.*
- (13) *In vitro diagnostic tests.*
- (14) *Any other similar device as defined in regulations adopted by the department.*

(c) The term "home medical device" does not include any of the following:

- (1) Devices used or dispensed in the normal course of treating patients by hospitals and nursing facilities, other than devices delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering home medical devices to an individual's residence.
- (2) Prosthetics and orthotics.
- (3) Automated external defibrillators (AEDs).
- (4) Devices provided through a physician's office incident to a physician's service.
- (5) Devices provided by a licensed pharmacist that are used to administer drugs that can be dispensed only by a licensed pharmacist.
- (6) Enteral and parenteral devices provided by a licensed pharmacist.

111656.13 (New)

(a) Any entity that prior to July 1, 2001, holds a current, valid license as a medical device retailer pursuant to Section 4130 of the Business and Professions Code, shall be deemed to be a licensed home medical device retail facility until the expiration of that license if the entity is in compliance with all applicable criteria for obtaining a license as a home medical device retail facility.

(b) *Any entity that was not required to obtain a license as a medical device retailer in order to provide equipment or services prior to July 1, 2001, and that is required to obtain a license as a home medical device retail facility pursuant to Section 111656, shall apply for a license as a home medical device retail facility by July 1, 2001; however, the requirement for licensure shall only apply to those entities on and after January 1, 2002.*

Civil Code**56.07 (New)**

(a) Except as provided in subdivision (c), upon the patient's written request, any corporation described in Section 56.06, or any other entity that compiles or maintains medical information

for any reason, shall provide the patient, at no charge, with a copy of any medical profile, summary, or information maintained by the corporation or entity with respect to the patient.

(b) A request by a patient pursuant to this section shall not be deemed to be an authorization by the patient for the release or disclosure of any information to any person or entity other than the patient.

(c) *This section shall not apply to any patient records that are subject to inspection by the patient pursuant to Section 123110 of the Health and Safety Code and shall not be deemed to limit the right of a health care provider to charge a fee for the preparation of a summary of patient records as provided in Section 123130 of the Health and Safety Code. This section shall not apply to a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or a disability insurer licensed pursuant to the Insurance Code. This section shall not apply to medical information compiled or maintained by a fire and casualty insurer or its retained counsel in the regular course of investigating or litigating a claim under a policy of insurance that it has written. For the purposes of this section, a fire and casualty insurer is an insurer writing policies that may be sold by a fire and casualty licensee pursuant to Section 1625 of the Insurance Code.*

56.10 (Amended)

(a) No provider of health care, health care service plan, or contractor shall disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan without first obtaining an authorization, except as provided in subdivision (b) or (c).

(b) A provider of health care, a health care service plan, or a contractor shall disclose medical information if the disclosure is compelled by any of the following:

- (1) By a court pursuant to an order of that court.
- (2) By a board, commission, or administrative agency for purposes of adjudication pursuant to its lawful authority.
- (3) By a party to a proceeding before a court or administrative agency pursuant to a subpoena, subpoena duces tecum, notice to appear served pursuant to Section 1987 of the Code of Civil Procedure, or any provision authorizing discovery in a proceeding before a court or administrative agency.
- (4) By a board, commission, or administrative agency pursuant to an investigative subpoena issued under Article 2 (commencing with Section 11180) of Chapter 2 of Part 1 of Division 3 of Title 2 of the Government Code.

(5) By an arbitrator or arbitration panel, when arbitration is lawfully requested by either party, pursuant to a subpoena duces tecum issued under Section 1282.6 of the Code of Civil Procedure, or any other provision authorizing discovery in a proceeding before an arbitrator or arbitration panel.

(6) By a search warrant lawfully issued to a governmental law enforcement agency.

(7) By the patient or the patient's representative pursuant to Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(8) When otherwise specifically required by law.

(c) A provider of health care, or a health care service plan may disclose medical information as follows:

(1) The information may be disclosed to providers of health care, health care service plans, contractor's or other health care professionals or facilities for purposes of diagnosis or treatment of the patient. This includes, in an emergency situation, the communication of patient information by radio transmission or other means between emergency medical personnel at the scene of an emergency, or in an emergency medical transport vehicle, and emergency medical personnel at a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(2) The information may be disclosed to an insurer, employer, health care service plan, hospital service plan, employee benefit plan, governmental authority, contractor or any other person or entity responsible for paying for health care services rendered to the patient, to the extent necessary to allow responsibility for payment to be determined and payment to be made. If (A) the patient is, by reason of a comatose or other disabling medical condition, unable to consent to the disclosure of medical information and (B) no other arrangements have been made to pay for the health care services being rendered to the patient, the information may be disclosed to a governmental authority to the extent necessary to determine the patient's eligibility for, and to obtain, payment under a governmental program for health care services provided to the patient. The information may also be disclosed to another provider of health care or health care service plan as necessary to assist the other provider or health care service plan in obtaining payment for health care services rendered by that provider of health care or health care service plan to the patient.

(3) The information may be disclosed to any person or entity that provides billing, claims management, medical data processing, or other administrative services for providers of health care or health care service plans or for any of the persons or entities specified in paragraph (2). However, no information so disclosed shall be further disclosed by the recipient in any way that would be violative of this part.

(4) The information may be disclosed to organized committees and agents of professional societies or of medical staffs of licensed hospitals, licensed health care service plans, professional standards review organizations, independent medical review organizations and their selected reviewers utilization and quality control peer review organizations as established by Congress in Public Law 97-248 in 1982, contractors or persons or organizations insuring, responsible for, or defending profes-

sional liability that a provider may incur, if the committees, agents, health care service plans, organizations, reviewers, contractors or persons are engaged in reviewing the competence or qualifications of health care professionals or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges.

(5) The information in the possession of any provider of health care or health care service plan may be reviewed by any private or public body responsible for licensing or accrediting the provider of health care or health care service plan. However, no patient identifying medical information may be removed from the premises except as expressly permitted or required elsewhere by law, nor shall that information be further disclosed by the recipient in any way that would violate this part.

(6) The information may be disclosed to the county coroner in the course of an investigation by the coroner's office.

(7) The information may be disclosed to public agencies, clinical investigators, including investigators conducting epidemiologic studies, health care research organizations, and accredited public or private nonprofit educational or health care institutions for bona fide research purposes. However, no information so disclosed shall be further disclosed by the recipient in any way that would disclose the identity of any patient or be violative of this part.

(8) A provider of health care or health care service plan that has created medical information as a result of employment-related health care services to an employee conducted at the specific prior written request and expense of the employer may disclose to the employee's employer that part of the information that:

(A) Is relevant in a lawsuit, arbitration, grievance, or other claim or challenge to which the employer and the employee are parties and in which the patient has placed in issue his or her medical history, mental or physical condition, or treatment, provided that information may only be used or disclosed in connection with that proceeding.

(B) Describes functional limitations of the patient that may entitle the patient to leave from work for medical reasons or limit the patient's fitness to perform his or her present employment, provided that no statement of medical cause is included in the information disclosed.

(9) Unless the provider of health care or health care service plan is notified in writing of an agreement by the sponsor, insurer, or administrator to the contrary, the information may be disclosed to a sponsor, insurer, or administrator of a group or individual insured or uninsured plan or policy that the patient seeks coverage by or benefits from, if the information was created by the provider of health care or health care service plan as the result of services conducted at the specific prior written request and expense of the sponsor, insurer, or administrator for the purpose of evaluating the application for coverage or benefits.

Law Update*Continued from Page 23*

(10) The information may be disclosed to a health care service plan by providers of health care that contract with the health care service plan and may be transferred among providers of health care that contract with the health care service plan, for the purpose of administering the health care service plan. Medical information may not otherwise be disclosed by a health care service plan except in accordance with the provisions of this part.

(11) Nothing in this part shall prevent the disclosure by a provider of health care or a health care service plan to an insurance institution, agent, or support organization, subject to Article 6.6 (commencing with Section 791) of Part 2 of Division 1 of the Insurance Code, of medical information if the insurance institution, agent, or support organization has complied with all requirements for obtaining the information pursuant to Article 6.6 (commencing with Section 791) of Part 2 of Division 1 of the Insurance Code.

(12) The information relevant to the patient's condition and care and treatment provided may be disclosed to a probate court investigator engaged in determining the need for an initial conservatorship or continuation of an existent conservatorship, if the patient is unable to give informed consent, or to a probate court investigator, probation officer, or domestic relations investigator engaged in determining the need for an initial guardianship or continuation of an existent guardianship.

(13) The information may be disclosed to an organ procurement organization or a tissue bank processing the tissue of a decedent for transplantation into the body of another person, but only with respect to the donating decedent, for the purpose of aiding the transplant. For the purpose of this paragraph, the terms "tissue bank" and "tissue" have the same meaning as defined in Section 1635 of the Health and Safety Code.

(14) The information may be disclosed when the disclosure is otherwise specifically authorized by law, such as the voluntary reporting, either directly or indirectly, to the federal Food and Drug Administration of adverse events related to drug products or medical device problems.

(15) Basic information including the patient's name, city of residence, age, sex, and general condition may be disclosed to a state or federally recognized disaster relief organization for the purpose of responding to disaster welfare inquiries.

(16) The information may be disclosed to a third party for purposes of encoding, encrypting, or otherwise anonymizing data. However, no information so disclosed shall be further disclosed by the recipient in any way that would be violative of this part, including the unauthorized manipulation of coded or encrypted medical information that reveals individually identifiable medical information.

(17) For purposes of disease management programs and services as defined in Section 1399.901 of the Health and Safety Code, information may be disclosed as follows: (A) to any entity contracting with a health care service plan or the health care

service plan's contractors to monitor or administer care of enrollees for a covered benefit, provided that the disease management services and care are authorized by a treating physician, or (B) to any disease management organization, as defined in Section 1399.900 of the Health and Safety Code, that complies fully with the physician authorization requirements of Section 1399.902 of the Health and Safety Code, provided that the health care service plan or its contractor provides or has provided a description of the disease management services to a treating physician or to the health care service plan's or contractor's network of physicians. Nothing in this paragraph shall be construed to require physician authorization for the care or treatment of the adherents of any well-recognized church or religious denomination who depend solely upon prayer or spiritual means for healing in the practice of the religion of that church or denomination.

(d) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no provider of health care, health care service plan contractor, *or corporation and its subsidiaries and affiliates* shall intentionally share, sell, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient.

(e) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no contractor *or corporation and its subsidiaries and affiliates* shall further disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan or insurer or self-insured employer received under this section to any person or entity that is not engaged in providing direct health care services to the patient or his or her provider of health care or health care service plan or insurer or self-insured employer.

56.11 (Amended)

Any person or entity that wishes to obtain medical information pursuant to subdivision (a) of Section 56.10, other than a person or entity authorized to receive medical information pursuant to subdivision (b) or (c) of Section 56.10, shall obtain a valid authorization for the release of this information. An authorization for the release of medical information by a provider of health care, a health care service plan, or contractor shall be valid if it:

(a) Is handwritten by the person who signs it or is in typeface no smaller than 8-point type.

(b) Is clearly separate from any other language present on the same page and is executed by a signature which serves no other purpose than to execute the authorization.

(c) Is signed and dated by one of the following:

(1) The patient. A patient who is a minor may only sign an authorization for the release of medical information obtained by a provider of health care, health care service plan, or contractor

in the course of furnishing services to which the minor could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60).

(2) The legal representative of the patient, if the patient is a minor or an incompetent. However, authorization may not be given under this subdivision for the disclosure of medical information obtained by the provider of health care, a health care service plan, or a contractor in the course of furnishing services to which a minor patient could lawfully have consented under Part 1 (commencing with Section 25) or Part 2.7 (commencing with Section 60).

(3) The spouse of the patient or the person financially responsible for the patient, where the medical information is being sought for the sole purpose of processing an application for health insurance or for enrollment in a nonprofit hospital plan, a health care service plan, or an employee benefit plan, and where the patient is to be an enrolled spouse or dependent under the policy or plan.

(4) The beneficiary or personal representative of a deceased patient.

(d) States the specific uses and limitations on the types of medical information to be disclosed.

(e) States the name or functions of the provider of health care, health care service plan, or contractor that may disclose the medical information.

(f) States the name or functions of the persons or entities authorized to receive the medical information.

(g) States the specific uses and limitations on the use of the medical information by the persons or entities authorized to receive the medical information.

(h) States a specific date after which the provider of health care, health care service plan, or contractor is no longer authorized to disclose the medical information.

(i) Advises the person signing the authorization of the right to receive a copy of the authorization.

California Code of Regulations

1707 Waiver Requirements for Off-Site Storage of Records

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver shall be granted to any entity licensed by the board for off-site storage of the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and

Professions Code.

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:

(1) maintain the storage area so that the records are secure, including from unauthorized access; and

(2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:

(1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or exemptee) and upon request to the board or any authorized officer of the law.

(2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.



How to find prices for Medi-Cal's top 50 prescription drugs

Quoting those Medi-Cal prescription drug prices for Medicare recipients may now be easier. When asked by a Medicare recipient for the Medi-Cal price for a prescription drug, provider pharmacies are required to quote the Medi-Cal price (reimbursement rate) even if the requestor does not purchase the prescription. Now, instead of making the patient wait until the prescription is "rung up" to learn the price, you can view a reimbursement price list of the 50 top Medi-Cal prescription drugs by accessing the Board's website (www.pharmacy.ca.gov). The Board has been advised by the Department of Health Services that the list will be updated approximately every month.

In February last year, a new law-Senate Bill 393 (Speier) Chapter 946, Statutes of 1999 and now found in the Business & Professions Code (B&PC) sections 4425-4427-was enacted entitling Medicare recipients to obtain prescription drugs at a cost no higher than the Medi-Cal reimbursement rate for those drugs, plus a fee set by the Department of Health Services to cover electronic transmission charges (B&PC 4425[a]). However, being able to research the prices on the Board's website will eliminate the electronic transmission charge of \$.18 that the pharmacy is charged per transaction when querying the system using a dummy account.

www.pharmacy.ca.gov

CHANGE OF ADDRESS FORM**Please fax to (916) 327-6308, 322-3561, 323-5743****Or mail to the California State Board of Pharmacy at the above address.***Please Print Clearly*

Licensee Name:	
License, Permit, or Registration Number (Please include prefix - RPH, INT, TCH)	
Present address of record: _____ _____	
Please change my address of record to: (May be post office box, personal mail box, business address, etc.) This address is accessible to the public via written request. All Board mailings-license renewal applications, license renewals, newsletters, notices, etc.-will go to this address. _____ _____	
Confidential residence street address must be listed if the address of record is not your residence address: _____ _____	
Social Security Number (for purposes of identification only)	Telephone number:
Signature of licensee:	Date:

This newsletter is published by the
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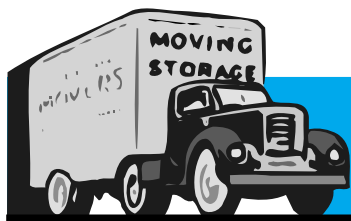
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Has your name or address changed?

Section 4100 of the Business and Professions Code requires all holders of personal Board-issued licenses (pharmacists, interns, pharmacy technicians and exemptees) to report name or address changes to the Board within 30 days of the change. **Such changes must be mailed or faxed to the Board.**

When notifying the Board of a change in your name, please include the following:

- ◆ A copy of legal documentation (marriage license, divorce decree, or legal name change) of your name change or
- ◆ Copies of your driver license **and** Social Security card (both reflecting the new name).

For address changes, please include your full name, license number, old address, and new address. **Your “address of record” is accessible to the public, pursuant to the Information Practices Act and the Public Records Act.** If you choose to use a post office box or business address as your address of record, section 1704 of the Business and Professions Code requires you to also provide your residence address which is *not* accessible to the public.

Please mail or fax all change information to:

California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento CA 95814
FAX: (916) 327-6308